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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,254	08/01/2006	Leon Rudakov	077567-0035	1195

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EXAMINER	
WOLF, MEGAN YARNALL	
ART UNIT	PAPER NUMBER
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,254	RUDAKOV ET AL.	
	Examiner	Art Unit	
	Megan Wolf	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11 and 17-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11 and 17-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *022310*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 5/10/10 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 6-9, 11, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang 6,379,382 (hereafter referred to as Yang).

Re claim 1, Yang discloses a medical device for insertion into a bodily vessel capable of treating an aneurysm having an aneurysm neck, the device comprising a mechanically expandable device 102 expandable from a first position to a second position (col.3, ll.16-20), wherein the mechanically expandable device is capable of being expandable radially outwardly to the second position such that the exterior surface of the mechanically expandable device engages with the inner surface of the vessel so as to maintain a fluid pathway through the vessel, a membrane 104 attached to the exterior surface of the mechanically expandable device, the membrane comprising a therapeutically effective amount of a chemical compound comprising a biosynthesis accelerator to stimulate cell growth (col.3, ll.47-49), the membrane capable of being placed such that it faces the aneurysm and releases the chemical compound

toward the aneurysm (col.5, ll.9-11), and a polymer mixed with the chemical compound to manage the release rate of the chemical compound (col.4, ll.13-17, 40-63; col.7, ll.9-18) wherein the mechanically expandable device is capable of providing a support for the release of the chemical compound within the aneurysm to stimulate cell growth within the aneurysm and close the aneurysm neck.

Re claims 6-9, 18, and 19, see col.4, ll.40-63.

Re claim 11, see figs.1, 3, and 5.

Re claim 17, see col.7, ll.9-18.

4. Claims 1, 9, 11, 17-19, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al. 6,093,199 (hereafter referred to as Brown).

Re claim 1, Brown discloses a medical device for insertion into a bodily vessel for treating an aneurysm having an aneurysm neck, the device comprising a mechanically expandable device 30 expandable from a first position to a second position (col.3, ll.13-27), wherein the mechanically expandable device is expandable radially outwardly to the second position such that the exterior surface of the mechanically expandable device engages with the inner surface of the vessel so as to maintain a fluid pathway through the vessel (fig.8), a membrane 70 attached to the exterior surface of the mechanically expandable device (col.7, ll.13-21; figs.5A,B), the membrane comprising a therapeutically effective amount of a chemical compound comprising a biosynthesis accelerator to stimulate cell growth (col.2, l.65-col.3, l.3; col.6, ll.18-63; col.10, ll.35-48), the membrane being configured such that it faces the aneurysm and releases the chemical compound toward the aneurysm (fig.8), and a polymer mixed with the

chemical compound to manage the release rate of the chemical compound (col.10, ll.35-48), wherein the mechanically expandable device provides a support for the release of the chemical compound within the aneurysm to stimulate cell growth within the aneurysm and close the aneurysm neck.

Re claims 9 and 17-19, see col.6, ll.60-63 and col.10, ll.39-43.

Re claim 11, see all figures and col.11, ll.22-25.

Re claim 25, Brown discloses using the medical device as claimed (see col.10, ll.1-15 and fig.8).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Yang or Brown as applied to claim 1 above, and further in view of Chatterjee 6,511,979 (hereafter referred to as Chatterjee). Yang and Brown disclose the invention substantially as claimed and as discussed above including that the therapeutic agent in the membrane stimulates cell growth. However, neither Yang nor Brown specifically discloses that the chemical compound is L-PDMP.

Chatterjee teaches a drug delivery device including a stent, in the same field of endeavor, wherein the cell growth stimulating agent is L-PDMP for the purpose of increasing proliferation of cells (col.7, ll.25-49).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use L-PDMP as the therapeutic agent in the devices of Yang or Brown, in order to increase the proliferation of cells as taught by Chatterjee.

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Yang or Brown as applied to claim 1 above, and further in view of Hossainy et al. 2004/0220665 (hereafter referred to as Hossainy). Yang and Brown disclose the invention substantially as claimed and as discussed above but do not specifically disclose that the drug delivering polymer is amorphous or semi-crystalline.

Hossainy teaches a drug delivery stent, in the same field of endeavor, wherein the polymeric membrane is semi-crystalline for the purpose of allowing for the active agent to diffuse out of the polymer (pars.44-45).

It would have been obvious to one of ordinary skill in the art at the time of the invention to specify that the polymer of Yang or Brown be at least semi-crystalline in order to allow the drug to diffuse out of the polymer and into the region that requires treatment.

8. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown as applied to claim 1 above, and further in view of Greene et al. 2002/0120276 (hereafter referred to as Greene). Brown discloses the invention substantially as claimed and as discussed above, and further discloses that portions of the device are formed of radiopaque materials in order to allow for visualization of the device during and post implantation (col.9, ll.3-10). However, Brown does not

specifically disclose that barium sulfate, zirconium dioxide, or iodine is incorporated in the polymer.

Greene teaches an aneurysm treatment device, in the same field of endeavor, wherein barium sulfate is incorporated into the drug delivery polymer for the purpose of making the device visible by conventional imagining techniques (par.53).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include radiopacifiers like barium sulfate in the polymer of Brown in order to visualize the device during and after implantation allowing for more precise placement of the device.

9. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Yang or Brown as applied to claim 1 above, and further in view of Hyodoh et al. 2003/0040772 (hereafter referred to as Hyodoh). Yang and Brown disclose the invention substantially as claimed and as discussed above but do not disclose that the stent is biodegradable or that the stent and polymer degrade at different rates.

Hyodoh teaches a stent, in the same field of endeavor, wherein the stent is biodegradable for the purpose of preventing the formation of emboli (par.210).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Yang or Brown to be biodegradable in order to allow for the stent to degrade within the bloodstream over a period of time to prevent the formation of emboli. It would have been further obvious that the stent degrade at a slower rate than the polymer delivering the drug in order to allow the necessary amount of active agent to be released prior to the degradation of the stent.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Wolf whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738
/David H Willse/
Primary Examiner, Art Unit 3738